4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-P-0170]

Determination That REQUIP XL (Ropinerole Hydrochloride) Extended-Release Tablets, 3 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ropinerole hydrochloride extended-release tablets, 3 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which

authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, are the subject of NDA 22-008, held by GlaxoSmithKline, and initially approved on June 13, 2008. REQUIP XL

is indicated for the treatment of treatment of signs and symptoms of idiopathic Parkinson's disease.

REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book. GlaxoSmithKline has never marketed REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg. In previous instances (see, e.g., 72 FR 9763, 61 FR 25497), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc. submitted a citizen petition dated April 1, 2009 (Docket No. FDA-2009-P-0170), under 21 CFR 10.30, requesting that the Agency determine whether REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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